

**REMARKS**

Claims 1, 4-7, 9-10, 12-14, and 45 are pending. The Applicant herein respectfully requests further examination of the application and reconsideration of the claims, in view of the amendments and remarks presented herein.

► The Applicant respectfully highlight the necessary distinction of the limitation of the amended claims presented herewith, i.e., directly monitoring volatile compounds in a gas or vapor phase medium during the polymerase chain reaction.

**ISSUES UNDER 35 USC §112, PARAGRAPH 2**

The Applicant herewith presents amendments to claim 1 to fully address the issues raised by the Examiner. Claim 1 now particularly points out and defines a method for directly monitoring volatile compounds in a gas or vapor phase medium from a nucleic acid polymerase chain reaction, during an accumulation cycle.<sup>1</sup> Claim 42 is cancelled.

The Applicant respectfully requests the Examiner to withdraw the rejection.

**REJECTIONS UNDER 35 USC §102**

**A. Van Ness '893 "Methods and compositions for determining the sequence of nucleic acid molecules"**

The Van Ness '893 disclosure provides a method for sequencing nucleic acids that fundamentally and necessarily requires, in the order, 1) separation of nucleic acid fragments according to size, 2) cleavage of a tag from the nucleic acid, and 3) detection of the tag. The Examiner's position is articulated that Van Ness discloses enzymatic cleavage and that the Applicant's previously claimed method has been indistinguishable. The Applicant respectfully amends the scope of the claims now pending to fully address this issue. Indeed, since all subject matter of the instant claims now pending is limited to a method for *directly* monitoring volatile

<sup>1</sup> See, e.g., Specification p. 11, lines 15-17; p.14, lines 4-7. See also, the Abstract of the Disclosure. DNA polymerase catalyzes the incorporation of the deoxynucleotide triphosphate into the DNA strand, if it is complementary to the base in the template strand. Each incorporation event is accompanied by release of pyrophosphate (PPi) in a quantity equimolar to the amount of incorporated nucleotide.

compounds in a gas or vapor phase medium from a nucleic acid *polymerase chain reaction*, during an accumulation cycle of the reaction, none of the claims encompass anything within the disclosure of Van Ness.

The Applicant therefore respectfully request the Examiner to withdraw the rejection under 35 USC §102 in view of Van Ness '893.

**B. Koster ('394) "Automated Process Line"**

The Applicant respectfully highlights that Anticipation under 35 USC §102 requires that every limitation of the claimed invention must be literally or inherently disclosed in a single prior art reference. Moreover, an anticipatory reference must also enable one of ordinary skill the practice the invention as claimed. The Applicant respectfully points out that the Koster '394 published application, cited as an *enabling* and anticipatory reference, is now abandoned.

**09/285,481 AUTOMATED PROCESS LINE**

|                         |                                  |                            |                                 |
|-------------------------|----------------------------------|----------------------------|---------------------------------|
| Application Number:     | 09/285,481                       | Customer Number:           | -                               |
| Filing or 371 (c) Date: | 04-02-1999                       | Status:                    | Abandoned -- Failure to Respond |
| to an Office Action     |                                  |                            |                                 |
| Application Type:       | Utility                          | Status Date:               | 06-04-2004                      |
| Examiner Name:          | SODERQUIST, ARLEN                | Location:                  | FILE REPOSITORY                 |
| (FRANCONIA)             |                                  |                            |                                 |
| Group Art Unit:         | 1743                             | Location Date:             | 06-15-2004                      |
| Confirmation Number:    | 3763                             | Earliest Publication No:   | US 2002-0009394 A1              |
| Attorney Docket Number: | 24736-2022                       | Earliest Publication Date: | 01-24-2002                      |
| Class / Subclass:       | 436/047                          | Patent Number:             | -                               |
| First Named Inventor:   | HUBERT KOSTER, LA JOLLA, CA (US) | Issue Date of Patent:      | -                               |
| Title of Invention:     | AUTOMATED PROCESS LINE           |                            |                                 |

Koster, however, does not teach or contemplate a method for directly monitoring volatile compounds in a gas or vapor phase medium from a polymerase chain reaction, during an accumulation cycle. The Examiner's position is, however, asserted: "possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." The Applicant respectfully points out that conclusory statements such as those here provided do not fulfill the agency's obligation. As explained in Zurko, 258 F.3d at 1385, 59 USPQ2d at 1697, that "deficiencies of the cited reference cannot be remedied by the Board's general conclusions about what is 'basic

knowledge' or 'common sense.'" The Board's findings must extend to all material facts and must be documented on the record, lest the "haze of so-called expertise" acquire insulation from accountability. The abandoned application of Koster indeed contemplates a robotic analytical system to integrate a myriad of possible instrumentalities, i.e., "[a] fully automated modular analytical system integrates instrumentation to permit analysis of biopolymer samples", and this all-encompassing language is used throughout the published application, no disclosure is present that describes a method for directly monitoring volatile compounds in a gas or vapor phase medium from a nucleic acid polymerase chain reaction, during an accumulation cycle of the reaction. It is improper, in determining whether a person of ordinary skill would have been led to a solution to a problem, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Koster paragraphs 108-125, as cited by the Examiner, merely contemplate a system in abstract terms that can evaluate a solid-phase reaction by means of mass spectrometry, *after* the reaction is completed. Koster, however, does not contemplate any embodiments that fall within the Applicant's claims now presented.

The Applicant, accordingly, respectfully requests the Examiner to withdraw the rejection.

### Rejections under 35 USC §103

The subject matter of claims 4-6 and 45 is rejected as obvious in view of the disclosure of Van Ness ('893) combined with Freidhoff ('115) and Van Ness ('893) combined with Koster ('394), respectively.

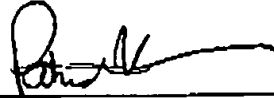
The Applicant respectfully point out the necessary distinction of the polymerase chain reaction limitation of the amended claims presented herewith, i.e., directly monitoring volatile compounds in a gas or vapor phase medium during the reaction. The '893 disclosure provides a method for sequencing nucleic acids that fundamentally and necessarily requires, in the order, 1) separation of nucleic acid fragments according to size, 2) cleavage of a tag from the nucleic acid, and 3) detection of the tag. The method of the present invention, in sharp contrast, is drawn toward a method for directly monitoring volatile compounds in a gas or vapor phase medium from a polymerase chain reaction, during an accumulation cycle of the reaction. This language patentably distinguishes now presented claims 4-6 and 45 to the instant invention.

The Applicant respectfully requests the Examiner to withdraw the rejections.

For all the foregoing reasons, the Applicant submits that Claims 1, 4-7, 9-10, 12-14, and 45 are in condition for allowance. Early action toward this end is courteously solicited.

The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

Respectfully submitted,



Patrick H. Higgins  
Reg. No. 39,709  
Attorney for Applicants  
(609) 896-7654

DATE: October 29, 2004

FOX ROTHSCHILD LLP, 997 Lenox Drive, Building 3, Lawrenceville, NJ 08648-2311